

## Section 1--Independent Assessment Procedure

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**Introduction**     The Independent Assessment Procedure addresses BUS Division's facilitation of independent assessments; documentation of the results of these activities; and tracking and resolution of issues and corrective actions resulting from findings, observations, or deficiencies that are noted during such assessments.

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**Policy**            BUS Division will be accountable for the formality of operations related to assessment activities that impact its operations.

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**Definition: corrective action**     A corrective action is the plan developed and action taken in response to an assessment finding, observation, or deficiency. An issue related to a corrective action, if managed effectively, will preclude recurrence (refer to Chapter 3, Section 2, Issue Management Procedure).

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**Definition: independent assessment**     An independent assessment is the process of evaluating operational activities that is performed by an agency independent from the organization being assessed, which can include but is not limited to audits, assessments, reviews, and surveillances. This includes assessments and audits performed by agencies external to the Laboratory.

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## **Responsibilities in Independent Assessments**

<b>BUS Division Office</b>	<b>BUS Division Office (BUS-DO) is responsible for supporting BUS personnel and processes that are affected by the conduct or outcome of an audit or assessment and is ultimately responsible for satisfactory compliance of mandated regulatory requirements by BUS Division.</b>
<b>Division Audit Coordinator</b>	<b>The Division Audit Coordinator (AC) is designated by BUS-DO to be responsible for coordinating personnel and activities associated with audits and assessments affecting BUS groups.</b>
<b>Issue coordinator</b>	<b>The issue coordinator is the person in the affected BUS group that coordinates the assignment of issue ownership and tracks corrective action commitments made by issue owners to ensure that accountability is maintained by the affected BUS group. The issue coordinator can serve as an issue owner.</b>
<b>Issue owner</b>	<b>The issue owner is responsible for ownership of corrective action issues related to audit and assessment findings and observations requiring corrective action.</b>

## How to Respond to Independent Assessment Notices

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**Overview** Notices of upcoming independent assessments are sent from the Laboratory Audits and Assessments Office (AA) to BUS-DO and are handled in the following manner.

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**Procedure** Upon receipt of an independent assessment notice, the following steps are taken:

Step	Action
1	BUS-DO determines if the notice directly impacts the Division and, if so, sends a copy to the AC.
2	The AC coordinates attendance at the assessment entrance conference with the affected BUS personnel (determined by the scope of the notice), introduces the assessors, and discusses the scope and schedule with all attendees.
3	The AC schedules all assessment interviews with the affected BUS personnel, as requested by the assessment team. If BUS personnel are asked by the assessment team to provide data, prior approval of this exchange must be granted by the next level of BUS supervision. The AC documents all data provided.
4	The AC coordinates attendance at the assessment exit conference with the affected BUS personnel to discuss the assessment team's preliminary findings, observations, and recommendations.
5	The AC reviews the assessment report for corrective action requirements and contacts the affected issue coordinators, who document these as issues and assign ownership.
6	Within 10 working days of being contacted by the AC, the assigned issue owner provides a proposed corrective action narrative to the AC for inclusion in the corrective action response.
7	The AC or his/her designee compiles all corrective action narratives into a corrective action response and transmits the report to the assessment team via AA .

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## How to Respond to Independent Assessment Notices, Continued

### Procedure (continued)

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Step	Action
8	The issue owner takes action consistent with the reported response and as required to close out the assessment finding/observation and notifies the issue coordinator and the AC.
9	The AC notifies AA when close-out status has been achieved and documents the assessment in a file for audit purposes.
10	The AC schedules interviews with issue owners at AA's request.

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